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08/378,939 01/26/95 CROWE

J 1809-118

EXAMINER

1801/0212

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ART UNIT 1816 PAPER NUMBER

1816

37

DATE MAILED: 02/12/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 11/14/96 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 7 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449. | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474. | 6. <input type="checkbox"/> |

Part II SUMMARY OF ACTION

- ☒ Claims 1-14 are pending in the application.
Of the above, claims _____ are withdrawn from consideration.
- ☒ Claims 15-31 have been cancelled.
- ☐ Claims _____ are allowed.
- ☒ Claims 1-14 are rejected.
- ☐ Claims _____ are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.
- ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes
- ☐ Formal drawings are required in response to this Office action.
- ☐ The corrected or substitute drawings have been received on _____ Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
- ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
- ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
- ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
- ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
- ☐ Other

EXAMINER'S ACTION

15. Claims 15-31 have been canceled.
16. Claims 1-14 are currently pending.
17. Claims 1 and 11 have been amended.
18. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Applicants' cancellation of Figure 1 is noted and is not deemed to introduce new matter. Applicants' request to hold in abeyance the formal drawing requirements is noted.
19. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.
21. Claims 1-2, 4-5, 7-10, 12-14 are rejected under 35 U.S.C. § 103 as being unpatentable over Gillies et al. The

invention is drawn to a process of recombinantly producing antibodies. Gillies et al. teach methods for the production of human (primate) antibodies (specifically anti-tetanus antibodies) from cDNA libraries, as well as transfected cell lines, transfecting vectors, and a recombinant human (primate antibody that would be useful for the treatment of tetanus poisoning (see Materials and Methods). Applicants' specification indicates that methods of inserting complete cDNA sequences into expression vectors were known before the time of invention of the claimed subject matter (see page 14, paragraph 2). Therefore it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to make recombinant antibodies as claimed by applicant according to Gillies et al.

Applicant's position that Gillies probably removed the 3' untranslated sequence is not supported by evidence that this in fact is what Gillies did. Applicant is also advised that the claims of this application are not commensurate in scope with the claimed invention in that the claim fails to recite the requirements that the polyA tail is introduced into the construct. The claims simply do not contain this limitation.

22. Claims 3 and 6 stand rejected under 35 U.S.C. § 103 as being unpatentable over Gillies et al. in view of Fount et al. (WO 87/01131) and Ehrlich et al. Applicant traverses on the grounds that Gillies et al. teach away from the claimed invention in that the insertion of intact cDNA is not taught. Applicant would appear to be arguing claim limitations not present. Even if such limitations were present, Applicants' specification indicates that methods of inserting complete cDNA sequences into expression vectors were known before the time of invention of the claimed subject matter (see page 14, paragraph 2). Applicants' claims, if amended to contain the argues limitations would be rejected under 35 USC 103 over Gillies et al. in view of the admitted prior art. Applicants' arguments have been considered but are not found persuasive.

Applicant relies on the deficiency of Gillies to render this rejection invalid, as discussed above this is not persuasive.

23. Claim 11 stands rejected under 35 U.S.C. § 103 as being unpatentable over Gillies et al. in view of Larrick et al. The claim is drawn to a method for the production of

recombinant antibodies using micro-preps of RNA. Applicant argues that Gillies et al. requires the use of genomic DNA encoding the heavy chain of Ig molecules. Applicants' arguments appear to be directed to unclaimed elements believed to define over the prior art. Even if such limitations were present, Applicants' specification indicates that methods of inserting complete cDNA sequences into expression vectors were known before the time of invention of the claimed subject matter (see page 14, paragraph 2). Applicants' claims, if amended to contain the argues limitations would be rejected under 35 USC 103 over Gillies et al. in view of the admitted prior art. No such limitations exist in the claims, accordingly applicants' arguments are not found persuasive.

Applicant relies on the deficiency of Gillies to render this rejection invalid, as discussed above this is not persuasive.

24. No claim allowed. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application may be subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, if this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192.

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THIS APPLICATION IS SUBJECT TO PUBLIC LAW 103-465.

Therefore, upon the timely filing of a first submission and the appropriate fee of \$750 for a large or ½ that amount for a small entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

25. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). THE CM1 FAX CENTER TELEPHONE NUMBER IS (703) 308-4242
26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Eisenschenk whose telephone number is (703) 308-0452. The examiner can normally be reached Monday through Thursday from 6:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.



February 6, 1997
Christopher Eisenschenk, Ph.D.
Primary Examiner
Group 1800